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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,113	12/04/2003	Guy Bemis	VPI/01-116 DIV US	7647
27916	7590	12/20/2005	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			RAO, DEEPAK R	
			ART UNIT	PAPER NUMBER

1624

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/728,113	Applicant(s) BEMIS ET AL.	
	Examiner Deepak Rao	Art Unit 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12042003</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

Claims 1-34 are pending in this application.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula I or pharmaceutically acceptable salt thereof, does not reasonably provide enablement for the “pharmaceutically acceptable derivatives” of compounds of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention; 2) the state of the prior art; 3) the predictability or lack thereof in the art; 4) the amount of direction or guidance present; 5) the presence or absence of working examples; 6) the breadth of the claims; and 7) the quantity of experimentation needed.

The instant claims recite “A compound ... or a pharmaceutically acceptable derivative thereof” wherein there is insufficient description in the specification regarding the types of ‘derivatives’ intended by the recitation. The recitation “pharmaceutically acceptable derivative” is explained in the specification at page 51 - ‘pharmaceutically acceptable derivative means any

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non-toxic salt, ester, salt of an ester or other derivative, which upon administration to a recipient, is capable of providing ... a compound of the present invention or an inhibitorily active metabolite or residue thereof. However, the specification does not provide what are some of the examples of "derivatives" intended by this recitation.

As explained in the specification, the recitation includes esters and amides of compounds of formula (I). However, the definition of various substituent groups in formula (I) already include such groups, i.e., acids, esters, amides, etc. The specification does not provide what other 'compounds' of the invention are intended to be the above-referred "derivatives". The generic formula of the claims already include both esters and the corresponding free acid forms, see e.g., see the term  $\text{CO}_2\text{R}$  wherein R is hydrogen, alkyl, etc. There is no disclosure regarding any other esters or amides that are capable of providing compounds of the invention. Further, specification does not provide sufficient explanation of the term "metabolite". A metabolite is any compound which is pharmaceutically active *in vivo* when it undergoes "metabolic" process and the specification does not provide any disclosure of what these compounds might be that *in vivo* transform in to the instantly claimed compounds. The specification does not provide what other 'compounds' of the invention are intended to be metabolites. Since functional groups such as esters, amides, etc. are already included in the claimed compounds, it is not clear whether compounds bearing these groups are excluded from being a potential "pharmaceutically acceptable derivatives" of the claimed invention. If compounds bearing these groups (i.e., ester, etc.), which are likely to undergo *in vivo* transformation, are excluded then what is included in the definition of the above term and where on the structural formula I are these groups placed; the specification does not provide any direction to one of ordinary skill in the art.

2. Claims 26-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition and method of treating rheumatoid arthritis, does not reasonably provide enablement for a composition to detectably inhibit Src or Lck protein kinase activity; a method of inhibiting Src or Lck kinase activity in a biological sample; or a method of treating or lessening the severity of all other diseases or conditions mediated by Src or Lck kinases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claim 26 is drawn to ‘a composition for inhibiting Src or Lck protein kinase activity and claim 28 is drawn to ‘a method of inhibiting Src or Lck kinase activity in a biological sample’. The examples 11-12 in the specification provide *in vitro* assays to measure the Src and Lck kinase inhibition activity of some of the exemplified compounds of the instant invention. The term “biological sample” is defined in the specification (page 58, lines 17-21) to ‘include,

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without limitation, cell cultures or extracts thereof; biopsied material obtained from a mammal or extracts thereof; and blood, saliva, urine, feces, semen, tears, or other body fluids or extracts thereof. As can be seen from the definition of the term, without limitation it reads on many types of biological samples, including mammals or animals and therefore, they are seen to encompass methods wherein the compound is administered to an animal. The instant claim appears to be a 'reach through' claim. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention.

The instant claims are drawn to "a method treating or lessening the severity of a Src- or Lck-mediated disease or condition in a patient" and the specification provides a wide list of diverse disorders based on kinase inhibiting activity, see page 59, lines 1+. First, the instant claims cover 'diseases' that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The use disclosed in the specification is as kinase inhibitors, useful to treat a laundry list of diseases, which include cancer, autoimmune diseases, allergic diseases, etc. Test assays and procedures are provided in the specification in Examples 11-12 related to Src and Lck kinase inhibition, wherein the inhibitory activity data for some of the compounds of the invention is provided in Table 10, however, there is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of the diverse disorders of the instant claims. The disorders encompassed by the instant claims include cancer, multiple sclerosis, etc., some of which have been proven to be extremely difficult to treat. Further, there

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is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, the instant claims recite treating of diseases mediated by Src or Lck kinases, and there is no disclosure regarding how all these assorted types diseases are treated. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art. Receptor activity is generally unpredictable and highly structure specific area, as evidenced by the wide range of results obtained for the tested compounds. It is inconceivable as to how the claimed compounds can treat the large list of diseases embraced by the claims having diverse mechanisms or inhibit Src or Lck kinases.

The instant claims are further drawn to 'treating cancer'. A 'cancer' or 'proliferative disorder' is anything that causes abnormal tissue growth. That can be growth by cellular proliferation more rapidly than normal, or continued growth after the stimulus that initiated the new growth has ceased, or lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such term covers not only all cancers, but also covers precancerous conditions such as lumps, lesions, polyps, etc. No compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states that "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the

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enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers'. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. In reference to cancer treatment using protein tyrosine kinase inhibitors, Traxler (Exp. Opin. Ther. Patents, 1997) stated that "pharmacological properties such as stability in biological media, bioavailability, metabolism or formulability are significant hurdles" see page 585, col. 2, lines 33-36.

Further, the list of the diseases includes multiple sclerosis, which has traditionally been very difficult or impossible to treat effectively with chemotherapeutic agents. See e.g., Casanova et al. (PubMed Abstract enclosed) state that "Multiple Sclerosis (MS) is a disorder in which the pathogenesis is not clearly understood", see the abstract. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein and therefore, require the treatment. Next, applicant's attention is drawn to the Revised Utility and Written Description Guidelines, at 66 FR 1092-1099, 2001 wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed 'treating or lessening the severity' effect of a 'disease' solely based on the inhibitory activity disclosed for the compounds.

Further, the claims recite treatment of 'allergic disease'. The number and complexity of allergenic triggers rise with each year that passes, the incidence of allergic diseases rises, and

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diseases like eczema have now reached epidemic proportions with no end in sight. Doctors and researchers struggle to find an effective therapeutic remedy, but so far have achieved only palliative remedies. Allergic reactions or diseases may involve any part of the body; the most frequently involved are the nose and chest with resultant symptoms of hay fever, rhinitis or asthma, respectively. The skin and eyes also commonly show allergic symptoms. Anaphylactic shock is a severe allergy, which affects many organs at the same time causing a rapid decrease in blood pressure, fainting and, occasionally, death. Allergies come in a variety of forms and vary in severity from mildly bothersome to life-threatening and there is no single method of treatment which is known to be effective against all types of allergies.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Traxler, in a recent article (Exp. Opin. Ther. Patents, 1997) stated that "The concept of the inhibition of growth factor receptor-mediated signal transduction via inhibition of its protein tyrosine kinase is a novel, **not yet proven** clinical approach to the regulation of cell proliferation.", see page 585, col. 1. Therefore, the state of the art provides the need of undue experimentation for the instantly claimed therapeutic benefits.

The instant claims 33 and 34 refer to an implantable device. Implants or implantable devices are artificial devices which made to replace and act as a missing biological structure. There are a lot of different implants which replace different functions in humans. Modern

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medical implants are generally high-end devices. Outer shell of implants made of bioinert materials, in most cases from titanium. In some cases implants contain electronics e.g. artificial pacemaker and cochlear implant. In other cases medical implants has compound structure and acts as reinforcement e.g. dental implant or knee joint replacement implant. The specification does not provide an enabling disclosure in what type of therapeutic application are the implantable devices used. Problems are often encountered in the use of implantable devices such as stents, due to the development of a thick endothelial tissue inside the lumen or neointima.

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements).

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

**Note:** The composition claims 26-27 and 33 are included in the above rejection because these claims recite a particular intended use for the composition. See MPEP § 2164.01(c). When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the

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entire scope of that claim is sufficient to preclude a rejection for non-enablement based on how to use.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In the claims, in the recitation “pharmaceutically acceptable **derivative**” (all occurrences), the term ‘derivative’ is open ended. The specification on page 51 provides an explanation that the recitation represents “any non-toxic salt, ester, salt of an ester or **other derivative**”, which again leaves it open ended. Further, the claimed compounds already include ‘ester’ groups among the substituents, see e.g., the definition of R<sup>1</sup> which can be C(O)OR wherein R is an aliphatic group. Therefore, it is not clear what is intended by the term ‘derivative’. Replacing ‘derivative’ with the positively recited term -- salt -- (all occurrences) is suggested.
2. Claim 1 recites the limitation “two R<sup>4</sup> on adjacent positions of the phenyl ring....” in page 76, lines 29-33. There is insufficient antecedent basis for this limitation in the claim. The structural formula I has only one R<sup>4</sup> substituent (see the formula in page 75) and therefore, it is not understood which R<sup>4</sup> is referred by this recitation.
3. In claim 27, following the recitation “an additional therapeutic agent”, the limitations: ‘a treatment of Alzheimer’s Disease, a treatment for Parkinson’s Disease’, etc. do not

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appear to be related to "an agent" *per se*. There is no 'agent' recitation associated with these limitations and therefore, it is confusing. The discrepancy also appears in claim 32.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al., WO 01/12621. The instantly claimed compounds read on the compounds disclosed in the reference, see the compounds of formula I wherein Q is pyrimidinyl and the species of Examples in Tables 1-6. The reference teaches that the compounds are useful in treating diseases associated with Src-family kinases, see page 48, lines 4-8.

The proviso statement (a) in claim 1 is acknowledged, however, the proviso does not require R<sup>1</sup> to be other than hydrogen when R<sup>3</sup> is ZQ<sub>n</sub>R<sup>7</sup> wherein n is 0. Accordingly, the instant claims read on the reference compounds.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al., WO 01/12621. The reference teaches a generic group of compounds, which embraces applicant's instantly claimed compounds. See formula I in page 8 wherein Q is pyrimidinyl; R<sup>1</sup> is T<sub>(n)</sub>-Ar<sup>2</sup> wherein Ar<sup>2</sup> is optionally substituted phenyl and the species of Examples in Tables 1-7. The compounds are taught to be useful as therapeutic agents, see pages 44-48. Claims 1-3, 5, 8 and 26-34 read on the compounds disclosed in the reference, see the rejection under 35 U.S.C. 102 above. The remaining claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as

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a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,693,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims substantially overlap the reference claims. See the reasons provided in the rejection under 35 U.S.C. 103.
2. Claims 1-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,689,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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instant claims substantially overlap the compounds of the reference claims. The reference compounds are encompassed by the instantly claimed genus, see formula (I) in claim 1 of the reference. The reference compounds are taught to be useful as therapeutic agents, see the disclosure. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have had the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

#### *Duplicate Claims*

Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 1 defines A-B to N-O or O-N and claim 2 merely shows the same in a structural diagram and therefore, both claims cover the same scope.

Receipt is acknowledged of the Information Disclosure Statement filed on December 4, 2003 and a copy is enclosed herewith.

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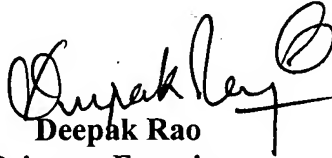
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deepak Rao  
Primary Examiner  
Art Unit 1624

December 9, 2005